Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13203

0 - FRONT

CFSAN

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN ___ of 1

Form Approved- OMB No 0910-0291 Expires 12/31/96
See OMB statement on reverse

FDA use only
Triage unit sequence # 92916
13203

A. Patient information

1. Patient Identifier	2. Age at time of event: 46 or Date of birth:	3. Sex	4. Weight
[redacted] In confidence		☒ female ☐ male	150 lbs or ___ kgs

B. Adverse event or product problem

1. ☒ **Adverse event** and/or ☐ **Product problem** (e.g , defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☒ life-threatening
- ☒ hospitalization
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other ___

3. **Date of event** (mo/day/yr) 11/13/98

4. **Date of this report** (mo/day/yr) 11/18/98

5. **Describe event or problem**

For two months, pt used four (4) Metabolife capsules daily in the morning and five (5) St Johns Wort daily at bedtime. She was mildy depressed She was also trying to lose weight (did lose 13 lbs). Thus this combination of self treatment. On 11/13/98, she experienced diplopia, fever of 102 F, and blood pressure of 200/130. (Reporter had seen her in April with normal BP of 130/80.) She was admitted to hospital due to fear of stroke potential. Pt received "a million dollar work-up" (see item B6 below). Suspected brain tumor or pheochromocytoma. Doing better now, no diplopia. Event abating slowly, still hypertension to contend with. Was put on Labetolol 600 mg BID and Norvasc 10 mg with hopes of d/c'ing soon.
The reporter had the bottle of Metabolife, mfg by Metabolife International, Inc., 5070 Sante Fe St, San Diego CA 92109. Ph. 619-490-5222. "Real big"capsules containing: "Vit E, magnesium, zinc, and chromium picolinate in a proprietary blend of 728 mg. Also contains Guarana concentrate 40 mg (natural occuring caffeine), ma huang 12 mg *-ephedrine - this is what reporter feels contributed mostly to event*, bee pollen, ginseng, ginger root, lecithin, bovine complex, damiana leaf, sarsaparilla root, goldenseal, nettles leaf, gotu kola, spirulina, and royal jelly. St Johns Wort bottle unavailable Dose and mfg unknown.

6. **Relevant tests/laboratory data**, including dates

With diplopia present, consulting neurologist prescribed MRI's to rule out a brain tumor. Various CAT scans including chest and abdomen. Various cultures done - negative.

7. **Other relevant history, including preexisting medical conditions** (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

White female NKDA. No known addictions. Mild depression, but otherwise healthy.

C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known)
- #1 Metabolife
- #2 St John's Wort

2. **Dose, frequency & route used**
- #1 See item B5
- #2

3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
- #1 See item B5
- #2

4. **Diagnosis for use** (indication)
- #1
- #2

5. **Event abated after use stopped or dose reduced**
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
- #1
- #2

7. **Exp. date** (if known)
- #1
- #2

8. **Event reappeared after reintroduction**
- #1 ☐ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. **NDC #** (for product problems only)
- – –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

None

RECEIVED
NOV 30 1998

D. Suspect medical device

1. **Brand name**

2. **Type of Device**

3. **Manufacturer name & address**

REC'D.
NOV 20 1998

4. **Operator of device**
- ☐ health professional
- ☐ lay user/patient
- ☐ other

5. **Expiration Date** (mo/day/yr)

6.
- **model #** MEDWATCH CTU
- **catalog #**
- **serial #**
- **lot #**
- **other #**

7. **If implanted, give date** (mo/day/yr)

8. **If explanted, give date** (mo/day/yr)

9. **Device available for evaluation?** (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. **Name & Address** [redacted] **phone #** [redacted]

2. **Health professional?** ☒ yes ☐ no

3. **Occupation** Physician

4. **Also reported to**
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. **If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box.** ☐

FDA

Mail to MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (1/96) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Taken By Telephone

000001

MDL
GTU 92916

UNITED STATES FOOD AND DRUG ADMINISTRATION

CONSUMER COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: BLT-8259

2. DATE OF COMPLAINT: 11/18/98

3. FORM OF COMPLAINT
(1) ☒ TELEPHONE (4) ☐ OTHER
(2) ☐ LETTER
(3) ☐ VISIT

4. SOURCE OF COMPLAINT
☐ CONSUMER ☐ TRADE SOURCE
☐ GOVERNMENT ☒ OTHER
☐ LOCAL ☐ STATE ☐ FEDERAL

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS: [redacted]
b TELEPHONE NUMBER
HOME: [redacted]
WORK: N/A

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY
Complaint was initially reported to FDA through MedWatch System from the patient's primary care physician. Complainant was taking product and had a severe adverse reaction. She was hospitalized for about 1 week. See attached imformation.

b DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? ☒ NO ☐ YES *(If Yes, explain in Remarks)*

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) ☒ YES
(If "yes" complete items a through d)

a. DEIO/EMOPS *(HFC-130)* NOTIFIED
(1) ☒ NO
(2) ☐ YES
DATE see remarks

b TYPE SYMPTOM ONSET (HR.)
(1) ☐ VOMITING
(2) ☐ NAUSEA
(3) ☐ DIARRHEA
(4) ☐ FEVER
(5) ☐ SKIN/EYE IRR.
(6) ☐ HEADACHE
(7) ☒ OTHER see att
Elevated Blood Pressure and other symptoms

c ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) ☒ YES
(If "yes, give name, address, phone)
[redacted]

d. HOSPITALIZATION REQUIRED
(1) ☐ NO (2) ☒ YES
(If "yes", give name, address, phone, date)
[redacted]

8. PRODUCT AND LABELING
a BRAND NAME: Metabolife
b PRODUCT NAME: Metabolife
c. SIZE AND PACKAGE TYPE: not known
d NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e LOT/SERIAL NUMBER: not known
EXP/USE BY DATE not known
f. DATE PURCHASED: not known
g PRODUCT USED (1) ☐ NO (2) ☒ YES
DATE
h. AMT REMAINING: None

9. MANUFACTURER/ DISTIBUTOR OF PRODUCT
a HOME DISTRICT: LOS-DO
b. CFN: None
c NAME AND LOCATION OF FIRM:
Metabolife International, Inc.
5070 Santa Fe Street
San Diego, CA 92109
619-490-5222
d IMPORT PRODUCT
(1) ☐ NO
(2) ☐ YES

10. EVAULATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX
(2) DESCRIPTION: Aderve Rea

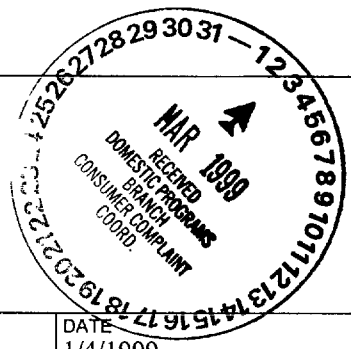
b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c DISPOSITION
(1) ☒ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY
(5) ☐ REFERRED TO STATE/ LOCAL AGENCY
(6) ☐ REFERRED TO OTHER FDA DISTRICT
(7) ☐ REFERRED TO OCI

11 PRODUCT CODE: 54YCA99

12. INFORMATION COPIES TO:
☐ HFC-130 ☐ HFD-730
☐ HFM-650 ☐ HFS-635
☐ HFV-210 ☐ HFZ-530
☐ OTHER

REMARKS
Not Reported to HFC-120, because initial report received through MedWatch.



NAME AND TITLE: Lawrence J. Stringer, CSO

DATE: 1/4/1999

FORM FDA 2516 (5/11/98)

000002

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: BLT-8259

2.a. ACTION REQUESTED
(1) ☒ INVESTIGATION
(2) ☐ COLLECT SAMPLE
(3) ☐ INSPECTION
(4) ☐ OTHER:

2.b. REMARKS *(Additional Details)*

2.c. REQUESTING OFFICIAL'S NAME AND TITLE	2.d. DATE REQUESTED	2.e. PROUCT NAME
Ronald Roy, Chief Domestic Programs Branch, CFSAN (HFS-636)	12/22/98	Metabolife

3.a. ASSIGNED TO:	3.b. DUE BY:	4.a. ACTION TAKEN	4.b. SAMPLE NUMBER(s)
Lawrence J. Stringer, CSO	1/22/99	(1) ☒ INVESTIGATION (2) ☐ SAMPLE COLLECTED (3) ☐ INSPECTION (4) ☐ NONE	

4.c. DESCRIPTION OF ACTION TAKEN

This complaint was originally logged as a MedWatch Report. I received the assignment on 12/31/98 (attached). On 1/4/99, I interviewed both the consumer and her primary care physician, who made the original report to MedWatch. I also collected the consumer's medical records (after receiving consent from the consumer) from her doctor. I completed an Adverse Event Questionnaire (attached). I also went to the hospital where the consumer was taken care of during this incident. I requested the consumer's medical records. On 1/15/99, I received the consumer's medical records from [redacted] All medical records are attached.

During my interview with the doctor, I found out about another incident. He provided me with an e-mail he received concerning it. The e-mail is attached.

The assignment requested labeling. No labels of the Metabolife product were available, except for the St. John's Wort. A copy is attached.

Documents are labeled on back with complaint number and initials (BLT-8259/LJS).

4.d. ACTION OFFICIAL'S NAME AND TITLE	4.e. ACTION DISTRICT	4.f. DATE COMPLETED
Lawrence J. Stringer, CSO	BLT-DO	1/22/99

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

5.a. HOME DIST.	5.c. NAME AND ADDRESS	6. PROGRAM DATA			
LOS-DO	Metabolife International, Inc. 5070 Santa Fe Street San Diego, CA 92109	6.a. OPERATION: 13	6.b. PAC: 03R801	6.c. PRODUCT CODE: 54YCA99	
CF NO.: None		6.d. EMP. HOME DIST.: 2	6.e. EMP. NO.: 819	6.f. POS CL.: 2	6.g. HOURS: 12

7. EVALUATION
(0) ☐ PENDING
(1) ☐ NO ACTION INDICATED (NAI)
(2) ☐ VOLUNTARY ACTION INDICATED (VAI)
(3) ☐ OFFICIAL ACTION INDICATED (OAI)
(4) ☐ NOT AN FDA OBLIGATION
(5) ☐ REFERRED TO HOME DISTRICT
(6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL
(7) ☐ REFERRED TO OCI

8. FINAL DISPOSITION
(1) ☐ FOLLOW-UP NEXT E1
(2) ☐ WARNING LETTER
(3) ☐ CITATION
(4) ☐ SEIZURE
(5) ☐ INJUNCTION / PROSECUTION
(6) ☐ REFERRED TO OTHER AGENCY
(Indicate Agency in Remarks)
(7) ☐ RECALL
(8) ☐ NO ACTION

9. INFO. COPIES TO:
☐ HFB-100
☐ HFD-730
☐ HFV-236
☐ HFZ-343
☐ HFC-161
☐ HFS-635
☐
☐
☐
☐
☐
☐
☐

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL	DISPOSITION	DISPOSITION DATE

FORM FDA 2516a (3/94)

Adverse Event Questionnaire

Complaint Number: _____ **Investigator:** STRINGER

Consumer Information

Date of Report: _____ MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury ☐Telephone ☐Correspondence ☐MedWatch ☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☒F ☐M Age: 46

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic ☐8-Other _____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 11/7/98
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): HOME

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):

How long did the symptoms last? ABOUT 2 WEEKS
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). 4 METABOLIFE IN MORNING
5 ST. JOHN'S WORT AT NIGHT

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
OCCASIONALLY ADVIL FOR HEADACHES
Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown AFTER 2 WKS
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number:

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist ☐Other (specify) _____

What medical tests were performed and what were the results?

What was the medical diagnosis? POSSIBLY HYPERTENSION RELATED TO METABOLIFE
What treatment(s) was given (e.g., drugs, other)? LABATALOL 600 mg

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies) and chronic diseases): ☒Yes ☐No ALLERGIC TO BEE STINGS

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object
(specify):_____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):
METABOLIFE. SEE MEDWATCH FORM.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown
SEE MEDWATCH REPORT. LABELS UNAVAILABLE

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame ☐Color Additive (please specify) _____
☐Monosodium Glutamate
☐Sulfite
☒Other DIETARY HERB, EPHEDRA
☐Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐Yes ☒No ☐Unknown Product Sample Available: ☐Yes ☒No ☐Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☒Yes ☐No

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) PROLONGED

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No

Did the adverse event result in a congenital anomaly: ☐Yes ☒No

TO: Lori Love, M.D., Ph.D

FROM: Constance J. Hardy

DATE: March 17, 1999

SUBJECT: ARMS 13203—Consumer Usage of Product

I verified with Ms. [redacted] on 3/17/99 that she took four tablets of the product Metabolife at one time in the morning. She stated the directions said to take up to 8 tablets. She also stated that the product she had taken had been thrown own by a relative of hers.